

In re Application of
David Sidransky
U.S. Serial No.: 09/420,433
Filed: October 12, 1999
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PATENT
Attorney Docket No.: JHU1180-1

I. AMENDMENTS

Please enter the following rewritten claims:

Sub D1
C
1. (Twice amended) A method for detecting the presence of a mammalian mutant target nucleic acid which contributes to the etiology of a neoplasm, in a tumor margin tissue specimen, wherein the specimen is external to a primary neoplasm and the specimen does not exhibit morphological characteristics indicative of neoplastic pathology, and the mutant target nucleic acid is present in the primary neoplasm and the specimen, the method comprising extracting nucleic acid present in the specimen and detecting the presence of the mutant target nucleic acid.

2. (Twice amended) The method of claim 1, further comprising, prior to detecting the presence of the mutant nucleic acid, amplifying the nucleic acid present in the specimen to produce an amplified nucleic acid, wherein said detecting comprises detecting the presence of the mutant target nucleic acid in the amplified nucleic acid.

C 2
11. (Twice amended) The method of claim 2, further comprising, prior to detecting the presence of the mutant nucleic acid, cloning the amplified nucleic acid, wherein said detecting comprises detecting the presence of the mutant target nucleic acid in the amplified nucleic acid.

Sub D2
12. (Twice amended) A method for detecting metastases in a subject having an excised tumor, the method comprising:
a) isolating tissue from a surgical margin adjacent to the excised tumor;
b) applying to said tissue an oligonucleotide that specifically hybridizes to a neoplastic nucleic acid having a mutant nucleotide sequence; and
c) detecting the presence of said neoplastic nucleic acid, wherein the presence of said neoplastic nucleic acid indicates metastases.

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Please add the following new claims:

GD DB

--19. A method for detecting a mammalian target neoplastic nucleic acid having a mutant nucleotide sequence in a tumor margin tissue specimen which is external to a primary neoplasm, comprising extracting nucleic acid present in the specimen to obtain extracted nucleic acid, and detecting the presence of the target neoplastic nucleic acid in the extracted nucleic acid.

C3

20. A method for detecting the presence of a mammalian mutant target nucleic acid which contributes to the etiology of a neoplasm, in a lymph node tissue specimen, wherein the specimen is external to a primary neoplasm and the specimen does not exhibit morphological characteristics indicative of neoplastic pathology, and the mutant target nucleic acid is present in the primary neoplasm and the specimen, the method comprising extracting nucleic acid present in the specimen and detecting the presence of the mutant target nucleic acid.

21. The method of claim 20, further comprising, prior to detecting the presence of the mutant nucleic acid, amplifying the nucleic acid present in the specimen to produce an amplified nucleic acid, wherein said detecting comprises detecting the presence of the mutant target nucleic acid in the amplified nucleic acid.

C3

22. The method of claim 20, wherein the mutant target nucleic acid contains a mutation selected from the group consisting of a restriction fragment length polymorphism, a nucleic acid deletion, and a nucleic acid substitution.

23. The method of claim 20, wherein the mutant target nucleic acid is selected from the group consisting of an oncogene and a tumor suppressor gene.

24. The method of claim 20, wherein the neoplasm is a neoplasm of the head or a neoplasm of the neck.

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Sub D5

C3
CX
C5N

25. A method for detecting metastases in a subject having an excised tumor, the method comprising:

- a) isolating tissue from a lymph node, which is external to a primary neoplasm and does not exhibit morphological characteristics indicative of neoplastic pathology;
- b) applying to said tissue an oligonucleotide that specifically hybridizes to a neoplastic nucleic acid having a mutant nucleotide sequence; and
- c) detecting the presence of said neoplastic nucleic acid, wherein the presence of said neoplastic nucleic acid indicates metastases.

26. The method of claim 25, wherein no more than an average of about one out of every ten thousand cells of said tissue have a neoplastic nucleic acid.

27. The method of claim 25, wherein said neoplastic nucleic acid is a mutated tumor suppressor gene.--